



## Lilly Announces Positive Results for Emgality® (galcanezumab-gnlm) from the CONQUER Study in Patients who Failed Previous Migraine Preventive Treatments

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**-Failure to respond to migraine preventive treatments is a common occurrence; internationally it is estimated that more than 40% of patients who use migraine preventive medications have a history of failure or switching treatments(1)**

INDIANAPOLIS, Aug. 5, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that Emgality® (galcanezumab-gnlm) met the primary and all key secondary outcomes in CONQUER, a Phase 3 study evaluating the efficacy and safety of Emgality in the preventive treatment of chronic and episodic migraine in patients with documented previous failures on two to four different standard-of-care migraine preventive medication categories, due to inadequate efficacy or for safety/tolerability reasons.<sup>2</sup>

The CONQUER study was designed and conducted based on findings from subgroup analyses of prior Phase 3 studies of Emgality, which suggested it may be an option for patients who self-reported failures on migraine preventive medications before study enrollment.<sup>3</sup>

"Preventive treatment failure has been a common occurrence among patients with migraine," said Gudarz Davar, M.D., vice president, neurology development, Lilly Bio-Medicines.<sup>1</sup> "The CONQUER study applied strict and rigorous criteria to identify and enroll patients with chronic and episodic migraine who had failed multiple migraine preventive treatments, with the goal of understanding whether Emgality may be an effective option for patients with such significant unmet need."

CONQUER was a Phase 3, double-blind, global study conducted in 12 countries. The study enrolled 462 patients with chronic (n=193, 41.7%) or episodic migraine (n=269, 58.2%) who had a history of documented treatment failures to two to four different standard-of-care migraine preventive medication categories.<sup>2</sup> Treatment failures were defined as inadequate efficacy after at least two months of treatment at the maximum tolerated dose, or discontinuation of the medicine for safety/tolerability reasons.<sup>2</sup> At baseline, patients had on average 13.2 monthly migraine headache days.<sup>2</sup> Following a screening period and prospective baseline period, eligible patients were randomized 1:1 to Emgality 120 mg per month (with a 240 mg loading dose) or placebo for three months of double-blind treatment.<sup>2</sup> Patients who completed the double-blind treatment phase could enter a three-month open-label treatment phase with Emgality.<sup>2</sup> The results below were analyzed from the three-month, double-blind period of the study.<sup>2</sup>

The study met its primary objective of demonstrating superiority of Emgality versus placebo in the overall mean change from baseline in the number of monthly migraine headache days across Months 1 through 3.<sup>2</sup> In the study, treatment with Emgality reduced monthly migraine headache days by 4.1 days (p<0.0001) compared with 1.0 day with placebo in the total (chronic and episodic migraine) study population.<sup>2</sup>

In addition, the study achieved statistical significance on all key secondary outcomes including

50%, 75% and 100% response rates and improvements in the Migraine-Specific Quality of Life Questionnaire Role Function-Restrictive (MSQ-RFR) domain.<sup>2</sup> The MSQ-RFR domain measures the degree to which migraine limits a person's daily social and work-related activities, including: feeling more energetic; feeling less tired for work or daily activities; concentrating better on work/daily activities; able to get more done at work and home; less difficulty performing work/daily activities; less interference in leisure activities and less interference dealing with family and friends.<sup>4</sup> The details of these key secondary outcomes will be presented at an upcoming scientific congress and published in a peer-reviewed journal.

The safety profile of Emgality observed in the CONQUER study was consistent with the safety profile observed in Phase 3 studies of patients with migraine and cluster headache treated with Emgality.<sup>2,5</sup>

### About Failures in Migraine Preventive Treatment

Review of the international treatment landscape indicates that, among all migraine preventive medication users, more than 40% have a history of previous preventive medication failure or of switching treatments; and inadequate treatment of migraine is associated with increased health care resource utilization.<sup>1,6,7</sup> Migraine is associated with an increase in outpatient visits, and the direct costs associated with health care resource utilization are even greater among patients with a history of switching and discontinuing multiple migraine preventive treatments.<sup>8,9,10</sup>

### About Emgality

Emgality is a monoclonal antibody that selectively binds to calcitonin gene-related peptide (CGRP) and was approved by the FDA in September 2018 for the preventive treatment of migraine in adults and in June 2019 for the treatment of episodic cluster headache in adults. Emgality was also approved in Europe in November 2018 for the prophylaxis of migraine in adults who have at least four migraine days per month.

### Indications and Usage for Emgality (galcanezumab-gnlm) Injection

Emgality is a calcitonin gene-related peptide (CGRP) antagonist indicated in adults for the:

- preventive treatment of migraine

- treatment of episodic cluster headache

## Important Safety Information

### Contraindications

Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

### Warnings and Precautions

#### Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, angioedema, dyspnea, urticaria, and rash, have been reported with Emgality. If a serious or severe hypersensitivity reaction occurs, discontinue administration of Emgality and initiate appropriate therapy. Hypersensitivity reactions can occur days after administration and may be prolonged.

#### Adverse Reactions

The most common adverse reactions (incidence  $\geq 2\%$  and at least 2% greater than placebo) in Emgality clinical studies were injection site reactions.

Please see [Full Prescribing Information](#), including [Patient Information](#), for Emgality. See Instructions for Use included with the device.

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### About Lilly's Commitment to Headache Disorders

For over 25 years, Lilly has been committed to helping people affected by headache disorders, investigating more than a dozen different compounds for the treatment of migraine and cluster headache. These research programs have accelerated our understanding of these diseases and furthered the advancement of our comprehensive late-stage development programs studying galcanezumab-gnlm, approved by the U.S. Food and Drug Administration for the preventive treatment of migraine in adults and the treatment of episodic cluster headache in adults, and lasmiditan, an investigational drug currently under review by the U.S. Food and Drug Administration for the acute treatment of migraine with or without aura in adults. Our goal is to apply our combined clinical, academic and professional experience to build a research portfolio that delivers comprehensive solutions and addresses the needs of people affected by these disabling neurologic diseases.

### About Eli Lilly and Company

Lilly is a global health care leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [lilly.com](http://lilly.com) and [lilly.com/newsroom](http://lilly.com/newsroom). P-LLY


This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Emgality (galcanezumab-gnlm) as a preventive treatment for patients with migraine and as a treatment for patients with episodic cluster headache and lasmiditan as a potential acute treatment for patients with migraine, and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that Emgality will receive additional regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

### References:

- <sup>1</sup> Pike J, Mutebi A, Shah N, Jackson J, Cotton S, Desai PR, Sapra S. Factors associated with a history of failure and switching migraine prophylaxis treatment: an analysis of clinical practice data from the United States, Germany, France, and Japan. *Value Health*. 2016;19(3):A68.
- <sup>2</sup> Data on file. July 2019.
- <sup>3</sup> Zhang Q, Ruff D, Pearlman E, Govindan S, Aurora K. Efficacy of Galcanezumab in Patients Who Failed to Respond to Preventives Previously: Results from EVOLVE-1, EVOLVE-2 and REGAIN Studies. *Neurology*. 2018;90(Suppl 15):S20.004.
- <sup>4</sup> Bagley CL, Rendas-Baum R, Maglinte GA, et al. Validating Migraine-Specific Quality of Life Questionnaire v2.1 in episodic and chronic migraine. *Headache*. 2012;52:3.
- <sup>5</sup> Emgality [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC.
- <sup>6</sup> Messali A, Sanderson JC, Blumenfeld AM, Goadsby PJ, Buse DC, Varon SF, Stokes M, Lipton RB. Direct and indirect costs of chronic and episodic migraine in the United States: a web-based survey. *Headache*. 2016;56(2):306-322.
- <sup>7</sup> Shah AM, Bendtsen L, Zeeberg P, Jensen RH. Reduction of medication costs after detoxification for medication-overuse headache. *Headache*. 2013;53(4):665-672.
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